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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,840	08/04/2003	Bernard Fritig	A34638-PCT-USA-I (072667)	1324
21003	7590	09/28/2004	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			IBRAHIM, MEDINA AHMED	
		ART UNIT	PAPER NUMBER	
			1638	

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/633,840	FRITIG ET AL.
	Examiner Medina A Ibrahim	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 August 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 17-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 17-33 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

Claims 17-33 are pending and are examined.

### *Title*

The title is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect that the claimed invention is drawn to a chimeric gene encoding a *Phytophthora* elicitor peptide and a method of using it.

### *Specification*

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS. See 37 CFR 1.78 and MPEP § 201.11.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT. See MPEP § 310.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) Or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.) See 37 CFR 1.52(e) and MPEP § 608.05
- (e) BACKGROUND OF THE INVENTION. See MPEP § 608.01(c).
  - (1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION. See MPEP § 608.01(d).

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification is specifically objected to for its omission of part (g). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74 are required. See MPEP § 608.01(f).

### ***Sequence Listing***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The sequence Listing filed 05/01/02 has been entered. However, the sequences on page 6, lines 1, 4, 11-12 and 25, and page 56, line 10, have not been identified by SEQ ID NO: Applicant is respectfully requested to identify the sequences presented on pages 6 and 56 or to submit a new Sequence Listing which comprises said sequences. Applicant is also required to amend the specification to include the SEQ ID NO: for said sequences. In addition, SEQ ID NO: 13 -14 are shown as DNA sequences in the

sequence listing and in the specification, but claimed as protein sequences. Appropriate correction is required.

***Claim Objections***

Claim 33 is an improper multiple dependent claim because it depends upon another multiple dependent claim 30. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18, 28-31, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86

USPQ 481 (Bd. App. 1949). In the present instance, claim 17 recites the broad recitation elicitor peptide, and the claim also recites "in particular an elicitors" which appears as the narrower limitation. Claim 31 recites the broad recitation monocotyledon and dicotyledonous, and the claim also recites "in particular cereals, sugar..." and "in particular tobacco, soybean, rapeseed, cotton..., which appears as the narrower limitations.

Claim 18 is indefinite in the recitation of "wherein the fungal elicitor peptide is megaspermine" because "megaspermine" is not an art-recognized term, and is not clearly defined in the specification. Therefore, the term is open to a variety of interpretations. Therefore, the metes and bounds of the claim are unknown.

Claims 28-29 are indefinite because "the transformed cells" lacks antecedent basis in claim 26, drawn to a transformed plant cell. Appropriate correction is required to more clearly define the metes and bounds of the claims.

Claim 30 is indefinite because "the plants" lacks antecedent basis in claims 29 and 33.

Claim 33 is indefinite because no plant is produced from the method of claim 25, drawn to a transforming plant cells. In addition, the recitation "using" without any steps involved in the method/process renders the claim indefinite. It is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 30-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. The claims do not read, "transformed grain", and therefore the claim reads on the product of nature. Due to chimerism, not all of the cells from a transgenic plant will comprise in their genome the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed plant/grain, it is unclear whether the claimed plant/grain would be distinguishable from plant/grain that would occur in nature. See *Diamond v. Chakrabarty* 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. Amendment to the claim to read ---transformed grain--- would obviate the rejection.

*Diamond v. Chakrabarty* 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. Amendment to the claim to read ---transformed grain--- would obviate the rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 17-18, 21, and 24-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Zitter et al (5,977,060, filed Feb 1998).

The claims are directed to a chimeric gene comprising a 5' regulatory region which is an inducible promoter, coding region that encodes a fungal elicitor/elicitors that is megaspermine and a 3' region; an expression vector comprising said chimeric gene, and a method for transforming plant cells with said chimeric gene, transformed plant /cells comprising said chimeric gene, and grain of said plant. Megaspermine is defined in here as any *phytophthora* elicitor fungal protein.

Zitter et al teach a chimeric DNA construct comprising a DNA molecule encoding an elicitor polypeptide from fungal *phytophthora*, operably linked to suitable regulatory sequences including an inducible promoter and 3' regulatory sequence functional in plant cells. Zitter et al teach transformation and regeneration of plants and transgenic plant and seed comprising said DNA, and plants propagated from said transgenic plant (columns 20-24, and claims).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-18, 21, and 24-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zitter et al (5,977,060, filed Feb 1998) in view of Applicant's admitted prior art (page 16 of the specification).

The claims are directed to a chimeric gene comprising specific inducible promoter, coding region that encodes a fungal elicitor/elicitins that is megaspermine, and 3' regulatory regions; an expression vector comprising said chimeric gene, and a method for transforming plant cells with said chimeric gene, transformed plant /cells comprising said chimeric gene, and grain of said plant.

Zitter et al teach a chimeric DNA construct comprising a DNA molecule encoding an elicitor polypeptide from fungal phytophthora, operably linked to suitable regulatory sequences functional in plant cells as discussed above.

Zitter et al do not teach the specific inducible promoters listed in claim 23. However, the use of said inducible promoters in plant transformation was known in the prior art before Applicant invention as evidenced by Applicant's own specification, page16. Therefore, the inclusion of one of said specific inducible promoters in the transformation vector would have been obvious with no unexpected results. Note, Applicant's unexpected results is limited to the use of SEQ ID NO: 13 and 14.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of unexpected results should be commensurate with the scope of the claims.

**Remarks**

Claims 19-20 and 22 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a chimeric gene comprising SEQ ID NO: 13 or 14, , a vector, plant cells and plants comprising said chimeric gene, nor that the prior art teaches a method of transforming plant cells with said chimeric gene.

No Claim is allowed.

**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/16/04

Mai

  
MEDINA A. IBRAHIM  
PATENT EXAMINER